

MAR 12 1996


SteriTec Products Mfg. Co., Inc.
CROSS-CHECKS Chemical Sterilization Process Indicator
FDA 510(k) Application
November 15, 1995
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510(k) SUMMARY

510(k) PREMARKET NOTIFICATION **SUMMARY**

510(k) Premarket Notification Summary

SUBMITTER:

- **STERITEC PRODUCTS MFG. CO., INC.**
680 Atchison Way - Suite 600
Castle Rock, CO 80104
(303) 660-4201
- Establishment Registration Number: 2028456
- Date November 20, 1995
- TOM ROLL
Printed name of person required to submit 510(k)
- 
Signature of person required to submit 510(k)
- PRESIDENT
Title of person submitting 510(k)

Proprietary Name: CROSS-CHECKS

Common/Usual Name: Steam Sterilization Process Indicator

Classification Name: Sterilization

Classification:

FDA has classified Physical/Chemical Sterilization Indicators in Class II under Classification Number 80JOJ, Regulation Number 880.2800.

Identification of Predicate devices:

Mr. Tim Ulatowski, Acting Director
Office of Device Evaluation - FDA
Response Letter to FDA 510(k) letter of January 24, 1996
RE: 510(k) Notification **Number K955426**
for the SteriTec Cross-Checks Steam/Vapor Process Indicator CI 105

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February 5, 1996

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The SteriTec product is similar in design, composition and function to the ATI Division of PyMah Corporation Sterilometer Steam Strip® chemical indicator strip for steam.

This predicate product was marketed prior to May 28, 1976.

Description of 510(k) submission device:

Intended use:

SteriTec CROSS-CHECKS Sterilization Process Indicators are a white to black chemical indicator strip that change color during steam or chemical vapor sterilization process. They are designed to be placed in each pack or package to be steam or chemical vapor sterilized, to indicate an item has been exposed to a steam or vapor process.

Comparison to Predicate device:

The basic formula and concept of chemical steam process indicators has not changed dramatically since they were invented in 1932.

Ink Composition Certification:

SteriTec certifies that the composition of this ink is basically the same as the ink formulation described in patent number 2,118,144 issued to Berman and Chaney on May 24, 1938 for a lead sulfide reaction. This reaction and the indicator strip described in the patent has been produced and marketed since the 1930's by the company they founded, Aseptic Thermo Indicator (ATI). ATI, now a division of the PyMah Corporation, uses this same formulation in the production of their Sterilometer Steam Strip® chemical indicator strip for steam. The only changes in the formula are variations in solvents to allow for the silk screen printing process used by SteriTec, Inc. versus Rotogravure printing process used by ATI Corporation. Please note: the solvents used in the formulation of the ink evaporate out during the manufacturing process.

Conclusion:

The SteriTec CROSS-CHECKS CI 105 is a white to black process indicator and it is essentially equivalent in construction and operation to the predicate device. Since the SteriTec Cross-Checks indicator is essentially equivalent in construction to the predicate device, it will perform in the same safe and effective manner, equivalent to the predicate device.